

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/699,212 Confirmation No.: 2780
Applicant : David R. Hennings et al.
Filing Date : October 30, 2003
Title : Endovenous Closure of Varicose Veins with Mid-Infrared Laser
Group Art Unit : 3735
Examiner : David M. Shay
Docket No. : 15487.4002
Customer No. : 34313

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REPLY BRIEF

Sir:

Introduction

The three issues identified by the Examiner at page 6 of his Examiner's Answer under the heading "Preface" will be discussed first in this Reply Brief. Those issues are:

1. Does Goldman Patent No. 6,258,084 contain an enabling disclosure with regard to laser treatment of varicose veins? (Answer: No)
2. Is the attempt by the Examiner to combine Dew Patent No, 4,854,320 and Sinofsky Patent No. 5,196,004 with Goldman improper? (Answer: Yes).
3. Has the Examiner improperly refused to consider the evidence relating to the real world of varicose vein treatment? (Answer: Yes).

This Reply Brief will then discuss several other issues raised by the Examiner's Answer.

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Discussion

A. Goldman Does Not Enable Laser Treatment of Varicose Veins

The Examiner acknowledges that the only mention of lasers in Goldman Patent No. 6,258,084 is at column 7, line 57 of that patent and it is as follows:

“...it is to be understood that other forms of energy (than RF) such as microwaves, ultrasounds, direct current, circulating heating fluid, radiant light, and lasers can be used...”

This disclosure in Goldman is so minimal that it borders on the nonexistent and falls far short of the requirement for an enabling disclosure.

In In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988), the Federal Circuit set forth eight factors relevant to the enablement analysis:

“(1) The quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.”

The single mention of lasers in Goldman, as but one alternative to RF heating, along with four other possible alternatives is nothing more than a statement of possibilities with no direction or guidance presented (Wands Factor No. 2). The remaining Wands factors are also unfulfilled. In order to implement laser technology in the treatment of varicose veins, an undue amount of experimentation (Factor No. 1) was necessary in order for applicant to arrive at the energy wavelength parameters set forth in the appealed claims, as demonstrated by the choice of different wavelengths by the prior art workers in the art. In addition, Goldman contains no working examples (Factor No. 3) with regard to the use of lasers, laser science is sophisticated and complex (Factor No. 4), the prior art (Navarro Patent No. 6,398,777 and the choices made by the prior art workers reflected in the attachments to the

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Hennings declaration) made different laser energy choices (Factor No. 5) than applicant, the relative skill in the art (Factor No. 6) is substantial as reflected in the literature articles attached to the Geriak declaration, and the unpredictability (Factor No. 7) of the effects of endovenous laser energy of different wavelengths on the tissue surrounding varicose veins was high. In addition, the appealed claims are not very broad (Factor No. 8), but are tailored to the laser energy range which distinguishes them from the prior art.

The Examiner's effort at pages 7 and 8 of the Examiner's Answer to rely on other prior art references, such as Sinofsky and Dew, to remedy the enablement deficiencies of Goldman is contrary to law as held in Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1366 (Fed. Cir. 1997):

“However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.”

That is precisely the situation which exists here with regard to the lack of enablement in Goldman of laser treatment of varicose veins. The single mention of lasers is nothing more than a starting point, and is plainly not an enabling disclosure.

One must look to a reference such as Navarro Patent No. 6,398,777 for an enabling disclosure for endovenous laser treatment of varicose veins. A comparison between the enabling disclosure of Navarro and the non-enabling disclosure of Goldman reveals a stark contrast between the two. However, the Examiner has declined to consider the undisputed evidence relating to the unfolding

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development of laser treatment of varicose veins and has instead gone far afield in his effort to rectify the non-enablement of Goldman with his resort to reliance on Dew and Sinofsky.

Dew is concerned with wound healing and Sinofsky is concerned with atherectomy. Thus, neither of these secondary references has anything to do with the other and neither of them has anything to do with the varicose vein treatment of Goldman. It is unreasonable in the extreme to suggest that a worker in the field of varicose vein treatment would, upon reading Goldman, and wondering how lasers might be used to treat such veins, to say "Aha, I will look at what has been done in wound healing and atherectomy".

In the present case, we do not have to wonder what this hypothetical worker in the art of varicose vein treatment would do. We know. What did happen in this regard is reflected in Navarro Patent No. 6,398,777, which discloses the use of a fundamentally different laser energy than that disclosed in Dew and Sinofsky.

B. The Combination of Dew and Sinofsky with Goldman is Improper.

The Examiner's argument in support of this combination collapses of its own weight. First, the Examiner makes the misstatement that both Dew and Sinofsky "are from the laser surgery field" which is not true of Dew (wound healing is not surgery) and essentially not true of Sinofsky which is directed to the opening up of blood vessels rather than closing them as disclosed in Goldman. The Examiner goes on to make the further misstatement that Goldman teaches the "removal or repair of tissue in tubular organs", neither of which is disclosed in Goldman who does not remove or repair anything. Rather, Goldman discloses closing varicose veins by destroying their functionality.

Even more important than these misstatements by the Examiner, which are not trivial, is the profound and undisputed fact that the references the Examiner attempts to combine have nothing to do

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with each other. The only reason this combination has been attempted is as an erroneous effort to reconstruct the invention claimed in the present application.

The Examiner's attempt to invoke the holding in KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (Sup. Ct., 2007) is seriously misplaced. In KSR, the references which were combined were all in the vehicle accelerator pedal art and the patentability issue revolved around replacing a mechanical pedal with an electronic pedal and with regard to the placement of a sensor in such pedal assemblies. In the present case, Goldman, Dew and Sinofsky are completely unrelated to each other. The fact that the Examiner has found it necessary to combine references which have nothing to do with each other is itself compelling evidence of the unobviousness of the appealed claims.

C. The Examiner Has Not Given Proper Consideration to the Evidence Submitted by Appellant.

Contrary to the Examiner's insistence that he has done so, the discussion at pages 8 and 9 of the Reply Brief demonstrate that he has not given proper consideration to the evidence submitted by Applicant. Two types of evidence were submitted. One body of evidence was a group of articles from the scientific literature attached to the Geriak declaration which teach away from the use of laser energy of the type employed by Appellant to treat varicose veins. The second body of evidence is the affidavit of the inventor, David Hennings and attachments to it, which states and demonstrates that, prior to the present invention, the prior art workers in the varicose vein treatment field acted in conformance with the views expressed in the scientific literature and did not use laser energy having the wavelength recited in the appealed claims for the treatment of varicose veins. Navarro Patent No. 6,398,777 is a third piece of evidence which is consistent with both the scientific literature and the activity of prior art workers as documented in the Hennings affidavit.

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The Examiner simply refuses to come to grips with this evidence. In his final rejection, the Examiner attempted to dismiss this evidence as “not statistically significant”, a total avoidance of the issues presented by the evidence. Now, in his Reply Brief, the Examiner again attempts to avoid meeting this issue by saying, at page 9:

“There is no assertion whatsoever in any affidavit of record that the articles or product literature are in any way representative of the prior art with respect to varicose vein treatment.”

These articles and product literature and the Navarro patent are much **more** than “representative” of the prior art, they **are the prior art**. The Examiner’s statement makes absolutely no sense and appears to be nothing more than a device for side-stepping the indisputable fact that the prior art teaches away from doing exactly what Appellant has done, namely, using laser energy in the range of about 1200 nm to about 1800 nm for treatment of varicose veins.

The Examiner’s reference to pages 2 and 3 of the Office Action of May 17, 2006 is equally unavailing. In that discussion, the Examiner did not come to grips with what the articles and product literature attached to the Geriak and Hennings’ Affidavits had to say, but rather attempted to wish them away by saying “there is no discussion of the 1320 nanometer of wavelength of Dew” and that Sinofsky shows “the knowledge in the art of the well known high absorption of wavelengths in the claimed range.” These statements by the Examiner have nothing to do with **what is said** in the articles and product literature, but rather simply make reference to the unrelated disclosures of Dew and Sinofsky. The directly relevant articles and product literature cannot be made to go away simply by making reference to the totally irrelevant Dew and Sinofsky references. In order to give Dew consideration to the evidence found in the articles and product literature, they must be considered for what they say and this has not been done.

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Thus, In re Sullivan, 498 F.3d 1345, 84 USPQ2d 1034 (Fed. Cir. 2007) is directly in point. The Examiner attempts to deflect the precedent pronounced in Sullivan by reference to post-decision events which he says occurred in later prosecution of the Sullivan application. That discussion is completely beside the point.

What it boils down to is this: the Examiner has presented no substantive response with regard to the evidence of patentability presented by the Appellant. Thus, it is respectfully requested that this Board give effect to that evidence and reverse the rejection of all claims.

D. There is no *prima facie* of Obviousness in the Present Appeal.

At page 10 of the Examiner's Answer, the Examiner asserts that he has established a *prima facie* case of obviousness. This is simply not so. Rather than *prima facie* obviousness, the rejection of claims 1, 2, 6, 7, 25, 35-38, 40-41 and 44-46 as unpatentable over Goldman in view of Dew and Sinofsky is based on an improper combination of unrelated references to create an artificial reconstruction of the claimed invention. This is the direct opposite of *prima facie* obviousness.

E. The Phantom Rejection

On page 11, heading V – “Claims 14 And 18 Are Obvious Over L’Esperance in Combination With Kohavakawa and Bille et al (“340)” comes out of the blue. None of these references are listed as the “Evidence Relied Upon” on page 3 of the Examiner’s Answer. Appellant has no idea what references the Examiner is referring to. The Examiner’s statement under this heading is also mysterious. The heading of this rejection refers to claims 14 and 18 but only claim 14 is mentioned in the text under the heading. This text makes it appear that the Examiner thinks that there is a “sensor” recited in claims 1 and 14 which is not the case and claim 18 has been canceled.

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F. Paragraphs II, III and IV on Page 11 of the Examiner's Answer

Appellant's Opening Brief discusses these rejections and nothing further need be said.

G. Claims 14-17 and 20-23 Are Not Obvious Over Makower in View of Roth and Dew

Makower is directed to the ablation of prostate tissue with laser energy. An important feature of the Makower device is the "locking means" 16 which is used to fix the location of laser energy emission which is disclosed at page 20 of Makower as follows:

"The interstitial locking means 16 insures that the light energy is applied at the same location as was the compound."

The Examiner appears to erroneously believe that the "fiber can be completely removed" during treatment (page 12 of Examiner's Answer), but this is not true. What is disclosed on page 20 of Makower is that:

"After cannula 12 is locked in place by locking means 16 and stylet 142 is removed, the cannula provides an ideal conduit for other treatments such as interstitially targeted drug therapy, radiation treatment by implantation of radioactive 'seeds', or implantation of microwave 'seeds' (essentially small metal strips) for subsequent application of microwave energy."

Thus, the stylet 142 which is removed is a rigid needle and not an optical fiber. Stated differently, Makower desires to deliver his laser energy to a fixed location whereas Roth uses a pull-back device to withdraw his laser energy means during treatment, which is used for treating the prostate.

Makower says nothing about the wavelength of laser energy which might be used. Roth, at column 12, line 33, discloses the use of energy having a wavelength of 1,064 nm. Roth and Makower are both directed to prostate treatment. However, the Examiner argues that it would be obvious to combine the unrelated wound healing technology of Dew with the ablation technology of Makower and

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Roth. No reason is given why this might be so and, of course, it is not. Thus, Roth cannot be properly combined with Makower and Dew cannot be properly combined with either.

H. Claim 19

The rejection of claim 19 as obvious over Makower in view of Roth, Dew and Conn is simply more of the same. Adding the diffuser of Conn to the apparatus of Makower is contra indicated because Makower's purpose is to target a tissue to be destroyed, not to diffuse laser energy over a wide area of tissue as in Conn.

I. The Examiner's Failure to Provide an Affidavit

Appellant has requested an affidavit by the Examiner under Rule 37 C.F.R. 1.104(d)(2) with regard to certain statements he has made because those statements find no support in the record.

Applicant requested an affidavit at page 9 of the amendment filed November 17, 2006 with regard to the Examiner's statement that he took "official notice" of "the problem of tissue adhesion" being "notorious in the art". The Examiner now argues that this request "is not seasonable" and then makes the statement that:

"Even assuming, arguendo, that the request was seasonable, this appears to be a moot point since Goldman et al. specifically teach the use of a pull-back mechanism."

Applicant submits that the foregoing statement is non-responsive to Applicant's request which went to the basis for the "official notice" taken by the Examiner.

The Examiner's statement with regard to his position on the statistical significance, or lack of it, of the literature articles submitted by Applicant is similarly non-responsive and demonstrates an erroneous view of statistical significance. Applicant believes the articles which have been submitted

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present an accurate view of the beliefs held by those skilled in the art with regard to desirable and undesirable wavelengths of laser energy to be used for varicose vein treatment prior to filing of the present application. The Examiner has not identified any articles which differ with those submitted. Thus, the articles which have been submitted are undisputed and are of overwhelming statistical significance because they stand uncontested.

Conclusion

The appealed claims have been rejected on the basis of a patchwork of unrelated references which the Examiner has attempted to combine based solely on the disclosure and claims of the present application. It is respectfully submitted that all of the rejections should be reversed.

Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

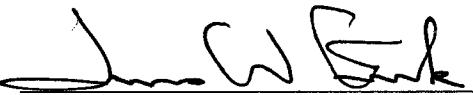
Respectfully submitted,

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